Supreme Court, U.S.
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No. 94-1832

In The

Supreme Court of the United States

October Term, 1994

SUBBY MARTELLO,

Petitioner,

v.

CIBA VISION CORPORATION,
A Georgia Corporation,

Respondent.

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Eighth Circuit

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Medical Device Amendments of 1976 – which expressly preempt state requirements relating to safety or effectiveness that are different from or in addition to federal requirements – bar state tort claims against the manufacturer of a Class III medical device whose use, labelling, manufacturing, sterilization, packaging and performance met the specific requirements imposed by the Food and Drug Administration as conditions of premarket approval?

CORPORATE AFFILIATES

Pursuant to Rule 29.1, the following is a list of all parent companies and subsidiaries of respondent CIBA Vision Corporation: Ciba-Geigy Corporation and CIBA Vision Group Management, Inc.

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STATEMENT OF THE CASE

Petitioner, Subby Martello, filed this action in state court alleging AOSEPT®, a contact lens disinfectant solution, allowed him to develop an eye infection which eventually resulted in a near-complete loss of vision in his right eye. Plaintiff's petition contained one cause of action asserting theories of recovery based on strict liability; negligence, including failure to warn; and breach of express and implied warranties.

After CIBA Vision removed the case to federal court, it filed a motion for summary judgment. Because AOSEPT® is a Class III medical device, CIBA Vision contended petitioner's claims were preempted by 21 U.S.C. § 360k of the Medical Device Amendments Act of 1976. That statute preempts state law claims that relate to the safety or effectiveness of a medical device and establish a requirement that is different from or adds to any requirement made applicable to the device by the Medical Device Amendments Act. The United States District Court for the District of Nebraska, the Honorable Lyle E. Strom, granted CIBA Vision's motion for summary judgment. The court ruled plaintiff's claims were preempted by 21 U.S.C. § 360k. The Eighth Circuit Court of Appeals affirmed. *Martello v. CIBA Vision Corp.*, 42 F.3d 1167 (8th Cir. 1994).

THE FEDERAL REGULATORY SCHEME PERTAINING TO MEDICAL DEVICES AND ITS APPLICATION TO CONTACT LENS SOLUTIONS.

The Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c-360l, gave the United States Food and

Drug Administration ("FDA") wide-ranging authority over medical devices. The amendments were enacted "to assure that medical devices . . . meet the requirements of safety and effectiveness before they are put in widespread use throughout the United States." S.Rep. No. 33, 94th Cong., 15 Sess. 2 (1975) *Reprinted in 1976* U.S. Code & Cong. News 1070, 1071.

The MDA established a three-tier system of device classification based upon the degree of regulation the FDA deems necessary for assurances of safety and effectiveness. 21 U.S.C. § 360c; 21 C.F.R. § 860.3(c). Class I devices generally do not present an unreasonable risk of injury, and are subject only to "general controls" relating to manufacture of the devices. *See* 21 U.S.C. § 360c(a)(1)(A). Class II devices, because of complexity in design or use, present a higher potential of risk of injury and may be subject to more strict regulation in the form of specific "performance standards." *See* 21 U.S.C. § 360c(a)(1)(B).

Class III devices – the most thoroughly regulated category – require premarket approval (PMA) by the FDA. The purpose of the PMA process is "to provide reasonable assurance of [the device's] safety and effectiveness." 21 U.S.C. § 360c(a)(1)(C). A device falls within class III if: (1) there is insufficient information to allow it to be classified as Class I or II; and (2) the device is to support or sustain human life, or "for a use which is of substantial importance in preventing impairment of human health . . . ;" or (3) it "presents a potential unreasonable risk of illness or injury." 21 U.S.C. §§ 360c(a)(1)(C)(i), (ii)(I), (II). Class III medical devices

cannot be sold to the public until they are approved by the FDA.

The PMA process for a Class III device is quite extensive. The procedure requires that the manufacturer submit to the FDA a detailed application on the device's design, intended use, components, properties and the principles of its operation; its manufacturing methods, packaging and its performance standards, if any; samples of the device; samples of the proposed labeling; and any other information deemed relevant by the FDA before marketing the product. The manufacturer must also submit all reasonably known scientific information bearing on the safety and effectiveness of the device. 21 U.S.C. § 360e(c); 21 C.F.R. § 814.20.

Each PMA application is then referred by the FDA to a panel of experts. 21 U.S.C. § 360e(c)(2). The FDA may either approve the device for sale or return the application for additional information or testing. 21 U.S.C. § 360e(d). Approval is granted if the FDA finds that there is a "reasonable assurance" that the device is "safe and effective," "weighing and probable benefit to health from the device against any probable risk of illness or injury from such use." 21 U.S.C. § 360c(a)(2); 21 C.F.R. § 860.7.

Once a Class III device has been approved for sale, it may not be manufactured, purchased, stored, labeled, distributed or advertised in a manner inconsistent with any conditions of approval specified in the PMA order approving the device. 21 C.F.R. § 814.80. In addition, the manufacturer must maintain certain records and report to the FDA regarding the device, particularly where the

manufacturer "becomes aware of information that reasonably suggests" that one of its devices "caused or contributed to a death . . . or serious injury," or malfunctioned in such a way likely to cause the same. 21 U.S.C. § 360i(1)(A), (B).

APPROVAL OF AOSEPT® AS A CLASS III MEDICAL DEVICE

CIBA Vision manufactures and distributes a contact lens disinfectant system called AOSEPT®, a medical device used to disinfect soft contact lenses. Soft contact lens disinfectant solutions are classified as Class III medical devices. 21 C.F.R. § 886.5928. As such, AOSEPT® had to undergo the premarket approval process under the MDA before it could be sold to the public.

AOSEPT® Catalytic Disinfection System was given premarket approval by the FDA under the name of SEPTICON® Disinfection Regimen ("SEPTICON®"). On July 29, 1982, the FDA approved for filing the Premarket Approval Application for SEPTICON®. On March 17, 1983, the FDA issued premarket approval for SEPTICON® for use in disinfecting SOFTCON® (Difacon A Contact Lenses) pursuant to FDA and applicable federal regulations. On April 8, 1983, the FDA published the announcement of its approval of SEPTICON® in the Federal Register, Volume 69, No. 69, pp. 15327-28. On December 23, 1983 the FDA issued premarket approval for SEPTICON® Disinfection Regimen for use with all soft, hydrophilic (contact lenses). On March 21, 1984, the FDA

was advised of a change in the product name from SEPTICON® Disinfection Regimen to AOSEPT® Catalytic Disinfection System. The PMA and corresponding FDA approvals for SEPTICON® Disinfection Regimen and AOSEPT® Disinfection System are owned by CIBA Vision Corporation. (Pet. App. 10.)

In addition to the normal PMA requirements, the FDA has specific regulations first promulgated in 1982 governing sterility and tamper-resistant packaging requirements of contact lens disinfectant solutions. 21 C.F.R. §§ 800.10, 800.12. Section 800.10 states that unsterile contact lens solution products are adulterated and potentially misbranded under the FDA. To reduce the risk of contamination of contact lens solutions, section 800.12 requires specific tamper-resistant packaging measures to be taken for contact lens solutions. It also specifies labeling which must accompany the product.

PROCEEDINGS BELOW

Petitioner conceded, as he does here, that AOSEPT® is a Class III medical device under the MDA. Petitioner also conceded, as he does here, that the FDA had approved the premarket application for AOSEPT® before he used it. Because AOSEPT® had been given premarket approval as a Class III medical device, CIBA Vision filed a motion for summary judgment in the district court. CIBA Vision argued all of the petitioner's state-law claims were expressly preempted by 21 U.S.C. § 360k(a).

In sustaining the motion, the district court analyzed petitioner's claims in accordance with this court's decisions in *CSX Transportation, Inc. v. Easterwood*, ___ U.S. ___, 113 S.Ct. 1732, 123 L.Ed.2d 387 (1993) and *Cipollone v. Liggett Group, Inc.*, 505 U.S. ___, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992). The district court correctly focused on the language of 21 U.S.C. § 360k to determine whether the federal statute preempts state or local requirements which pertain to an area of law traditionally governed by state law. As required by *Cipollone*, he concluded 21 U.S.C. § 360k(a) preempts not only state statutes and regulations but also state common law claims because such actions impose "requirements" within the meaning of the statute.

The district court also noted the FDA's view, as expressed in the agency's regulations, that 21 U.S.C. § 360k(a) applies to any requirement having the force and effect of law, whether "established by statute, ordinance regulation or court decision." 21 C.F.R. § 808.1(b). The court then analyzed petitioner's claims and determined that his claims of strict liability, breach of warranty, negligence, and failure to warn were all predicated on the safety or effectiveness of AOSEPT® and would have imposed requirements different from or in addition to those imposed by the FDA and thus were expressly preempted.

The Eighth Circuit Court of Appeals affirmed. That court agreed a state tort claim is preempted only if (1) the FDA has established regulations specific to the medical device in issue, (2) the state claim imposes a requirement different from, or in addition to, any FDA requirement for the device, and (3) the claim relates to the safety or

effectiveness of the device, or to any other matter included in an MDA requirement for the device.

As he does here, petitioner contended his claims were not preempted because the FDA's regulations contained no specific requirements for soft contact lens disinfection systems. The Eighth Circuit disagreed. The court concluded the premarket approval process is a specific requirement for a Class III device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d). The Eighth Circuit observed that FDA approval of a premarket application shows the FDA has reviewed a device's testing, design specifications, intended use, manufacturing method, performance standard and labelling, and decided the device is safe and effective. The court concluded the MDA expressly preempts state tort claims involving the safety and effectiveness of Class III medical device when the claims would impose additional requirements in areas governed by the premarket approval process. Because all of petitioner's state tort claims dealt directly with AOSEPT®'s safety and effectiveness and would add requirements in areas reviewed in the premarket approval process, the court concluded petitioner's claim was expressly preempted. It affirmed the district court's grant of summary judgment to CIBA Vision.

REASONS FOR DENYING THE PETITION

The decision of the Eighth Circuit Court of Appeals is correct. It does not conflict with the decisions of this Court or any other appellate court. The petition should therefore be denied.

The application of 21 U.S.C. § 360k to approved Class III medical devices such as AOSEPT® represents a straight-forward exercise in express preemption. There can be little doubt that 21 U.S.C. § 360k preempts state tort actions with respect to Class III devices that are subject to premarket approval requirements – nearly every court squarely to address the issue has so held. Including the Eighth Circuit in this case, four federal courts of appeal have now so held.

This Court denied certiorari after the Seventh Circuit ruled that 21 U.S.C. § 360k protects manufacturers of Class III devices from state tort claims that implicate requirements different from those imposed by the FDA. *Slater v. Optical Radiation Corp.*, 961 F.2d 1330, 1333 (7th Cir. 1992), *cert. denied*, ___ U.S. ___, 113 S.Ct. 327, 121 L.Ed.2d 246 (1992). This Court also denied certiorari in *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993), *cert. denied*, ___ U.S. ___, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993) and *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir. 1993), *cert. denied*, ___ U.S. ___, 114 S.Ct. 84, 126 L.Ed.2d 52 (1993). In those decisions, the Fifth and First Circuit Courts of Appeal had ruled that state tort liability that would impose a requirement different from or in addition to the PMA process for Class III medical devices is pre-empted. *Accord Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994); *Talbott v. C.R. Bard*, 865 F.Supp. 37, 51 (D. Mass. 1994); *Brown v. Medtronic, Inc.*, 852 F.Supp. 717, 719-20 (S.D.Ind. 1994); *Bravman v. Baxter Healthcare Corp.*, 842 F.Supp. 747, 760-61 (S.D.N.Y. 1994); *Kemp v. Pfizer*, 835 F.Supp. 1015, 1020 (E.D. Mich. 1993); and *Covey v. Surgidev Corp.*, 815 F.Supp. 1089, 1095 (N.D. Ohio 1993).

Petitioner's argument that no federal regulation or statute has set safety standards for contact lens disinfectant solution rests on a fundamental misapprehension of the federal regulatory scheme for Class III medical devices as was extensively considered and rejected below. By 21 U.S.C. § 360k, Congress expressly preempted competing state requirements:

> "[N]o state or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act."

21 U.S.C. § 360k(a). In this case, petitioner's state law tort claim would erect "requirements" beyond those specifically established by the FDA and are therefore preempted.

Class III medical devices are subject to the most extensive level of federal regulation and to the most specific requirements governing all aspects of their design and labelling. The manufacturer must submit full information on these and other aspects to the FDA before marketing and commercial distribution can proceed. The approval represents a license to market the product in accordance with the precise conditions specified by the FDA to insure the safety and effectiveness of the device. *See* 21 U.S.C. § 360e. These conditions – which specify

how the particular device in question must be manufactured and labeled – are the "requirements" that cannot be supplanted by states under 21 U.S.C. § 360k. As the FDA itself has written, state requirements are preempted when the FDA has "established specific counterpart regulations or there are other specific requirements applicable to a particular device under the Act." 21 C.F.R. § 808.1(d).

The Eighth Circuit may have explained it best:

> "FDA approval of a premarket application shows the FDA has reviewed a device's testing, design specifications, intended use, manufacturing method, performance standard, and labelling, *see* 21 U.S.C. § 360e(c)(1), and decided the device is safe and effective, *see id.* § 360c(a)(2). Here, all of [petitioner's] state tort claims deal directly with AOSEPT®'s safety and effectiveness and would add requirements in areas reviewed in the premarket approval process."

42 F.3d, at 1169.

CONCLUSION

On the basis of the well-reasoned opinions of the courts below, as well as for the reasons stated in this brief, respondent CIBA Vision Corporation respectfully requests the petition be denied.

Respectfully submitted,

CIBA VISION CORPORATION,
Respondent,

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